Syllabus.

GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL. *v.* TOILET GOODS ASSOCIATION, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT.

No. 438. Argued January 16, 1967.—Decided May 22, 1967.

The Commissioner of Food and Drugs, by delegation from the Secretary of Health, Education, and Welfare, issued three regulations under the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act, which the respondents challenge in a pre-enforcement action on the ground that the Commissioner impermissibly expanded the reach of the statute. The regulations (1) amplified the statutory definition of color additives by including diluents therein, (2) included certain cosmetics within the scope of color additives, and (3) limited the exemption for hair dyes to those as to which the "patch test" is effective and excluded from the exemption certain components other than the coloring ingredient of the dye. The Court of Appeals affirmed the District Court's judgment that it had jurisdiction to hear the suit. See *Toilet Goods Assn.* v. *Gardner, ante,* p. 158. *Held:* Under the standards set forth in *Abbott Laboratories* v. *Gardner, ante,* p. 136, namely, the appropriateness of the issues for judicial determination and the immediate severity of the regulations' impact on the respondents, the pre-enforcement challenge to these regulations is ripe for judicial review. Pp. 170–174.

(a) The issue as framed by the parties, what general classifications of ingredients fall within the coverage of the Color Additive Amendments, is a straightforward legal one, the consideration of which would not necessarily be facilitated if it were raised in the context of a specific attempt to enforce the regulations. Pp. 170–171.

(b) These regulations, which are self-executing, have an immediate and substantial impact on the respondents, providing extensive penalties and substantial preliminary paper work, scientific testing, and recordkeeping for the cosmetic manufacturers. Pp. 171–174.

360 F. 2d 677, affirmed.

Nathan Lewin argued the cause for petitioners. With him on the briefs were *Solicitor General Marshall, As-*

sistant Attorney General Vinson, Beatrice Rosenberg, Jerome M. Feit and *William W. Goodrich.*

Edward J. Ross argued the cause and filed a brief for respondents.

MR. JUSTICE HARLAN delivered the opinion of the Court.

In *Toilet Goods Assn.* v. *Gardner, ante,* p. 158, we affirmed a judgment of the Court of Appeals for the Second Circuit holding that judicial review of a regulation concerning inspection of cosmetics factories was improper in a pre-enforcement suit for injunctive and declaratory judgment relief. The present case is brought here by the Government seeking review of the Court of Appeals' further holding that review of three other regulations in this type of action was proper. 360 F. 2d 677. We likewise affirm.

For reasons stated in our opinion in *Abbott Laboratories* v. *Gardner, ante,* p. 136, we find nothing in the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, as amended), 21 U. S. C. § 301 *et seq.*, that precludes resort to the courts for pre-enforcement relief under the Administrative Procedure Act, 5 U. S. C. §§ 701–704 (1964 ed., Supp. II), and the Declaratory Judgment Act, 28 U. S. C. § 2201. And for reasons to follow, we believe the Court of Appeals was correct in holding that the District Court did not err when it refused to dismiss the complaint with respect to these regulations.

The regulations challenged here were promulgated under the Color Additive Amendments of 1960, 74 Stat. 397, 21 U. S. C. §§ 321–376. These statutory provisions, in brief, allow the Secretary of Health, Education, and Welfare and his delegate, the Commissioner of Food and Drugs, 22 Fed. Reg. 1051, 25 Fed. Reg. 8625, to prescribe conditions for the use of color additives in foods, drugs, and cosmetics. The Act requires clearance of every color additive in the form of a regulation prescribing condi-

tions for use of that particular additive, and also certification of each "batch" unless exempted by regulation. A color additive is defined as "a dye, pigment, or other substance . . . [which] when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto . . . ," 21 U. S. C. § 321(t)(1).

Under his general rule-making power, § 701 (a), 21 U. S. C. § 371 (a), the Commissioner amplified the statutory definition to include as color additives all diluents, that is, "any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body." 21 CFR § 8.1 (m). By including all diluents as color additives, the Commissioner in respondents' view unlawfully expanded the number of items that must comply with the premarketing clearance procedure.

The Commissioner also included as a color additive within the coverage of the statute any "substance that, when applied to the human body results in coloring . . . unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives.'" 21 CFR § 8.1 (f). Respondents alleged that in promulgating this regulation the Commissioner again impermissibly expanded the reach of the statute beyond the clear intention of Congress.

A third regulation challenged by these respondents concerns the statutory exemption for hair dyes that conform to a statutory requirement set out in § 601 (e), 21 U. S. C. § 361 (e). That requirement provides that hair dyes are totally exempt from coverage of the statute if they display a certain cautionary notice on their labels

prescribing a "patch test" to determine whether the dye will cause skin irritation on the particular user. The Commissioner's regulation recognizes that the exemption applies to the Color Additive Amendments, but goes on to declare: "If the poisonous or deleterious substance in the 'hair dye' is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to the poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair." 21 CFR § 8.1 (u).

Respondents contend that this regulation too is irreconcilable with the statute: whereas the statute grants an across-the-board exemption to all hair dyes meeting the patch-test notice requirement, the regulation purports to limit that exemption to cover only those dyes as to which the test is "effective." Moreover, it is said, the regulation appears to limit the exemption only to the coloring ingredient of the dye, and to require clearance for all other components of a particular hair dye.

We agree with the Court of Appeals that respondents' challenge to these regulations is ripe for judicial review under the standards elaborated in *Abbott Laboratories* v. *Gardner, supra,* namely the appropriateness of the issues for judicial determination and the immediate severity of the regulations' impact upon the plaintiffs.

The issue as framed by the parties is a straightforward legal one: what general classifications of ingredients fall within the coverage of the Color Additive Amendments? Both the Government and the respondents agree that for any color additive, distribution is forbidden unless the additive is (1) listed in a Food and Drug Administration regulation as safe for use under prescribed conditions, and (2) comes from a "certified" batch, unless

specifically exempted from the certification requirement. The only question raised is what sort of items are "color additives." The three regulations outlined above purport to elaborate the statutory definition; they include within the statutory term certain classes of items, *e. g.*, diluents, finished cosmetics, and hair dyes, that respondents assert are not within the purview of the statute at all. We agree with the District Court and the Court of Appeals that this is not a situation in which consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations.[1] Rather, "to the extent that they purport to apply premarketing requirements to broad categories like finished products and non-coloring ingredients and define the hair-dye exemption, they appear, *prima facie,* to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency." 360 F. 2d, at 685.

For these reasons we find no bar to consideration by the courts of these issues in their present posture. *Abbott Laboratories* v. *Gardner, supra; United States* v. *Storer Broadcasting Co.,* 351 U. S. 192; *Frozen Food Express* v. *United States,* 351 U. S. 40.

This result is supported as well by the fact that these regulations are self-executing, and have an immediate and substantial impact upon the respondents. See *Abbott Laboratories* v. *Gardner, ante,* pp. 152–153. The Act, as noted earlier, prescribes penalties for the distribution of

[1] We use "necessarily" advisedly, because this case arises on a motion to dismiss. The District Court also denied respondents' motion for summary judgment, and called for an evidentiary hearing. If in the course of further proceedings the District Court is persuaded that technical questions are raised that require a more concrete setting for proper adjudication, a different issue will be presented.

goods containing color additives unless they have been cleared both by listing in a regulation and by certification of the particular batch. Faced with these regulations the respondents are placed in a quandary. On the one hand they can, as the Government suggests, refuse to comply, continue to distribute products that they believe do not fall within the purview of the Act, and test the regulations by defending against government criminal, seizure, or injunctive suits against them. We agree with the respondents that this proposed avenue of review is beset with penalties and other impediments rendering it inadequate as a satisfactory alternative to the present declaratory judgment action.

The penalties to which cosmetics manufacturers might be subject are extensive. A color additive that does not meet the premarketing clearance procedure is declared to be "unsafe," § 706 (a), 21 U. S. C. § 376 (a), and hence "adulterated," § 601, 21 U. S. C. § 361 (e). It is a "prohibited act" to introduce such material into commerce, § 301, 21 U. S. C. § 331, subject to injunction, § 302, 21 U. S. C. § 332, criminal penalties, § 303, 21 U. S. C. § 333, and seizure of the goods, § 304 (a), 21 U. S. C. § 334 (a). The price of noncompliance is not limited to these formal penalties. Respondents note the importance of public good will in their industry, and not without reason fear the disastrous impact of an announcement that their cosmetics have been seized as "adulterated."

The alternative to challenging the regulations through noncompliance is, of course, to submit to the regulations and present the various ingredients embraced in them for premarketing clearance. We cannot say on this record that the burden of such a course is other than substantial, accepting, as we must on a motion to dismiss on the pleadings, the allegations of the complaint and supporting affidavits as true. The regulations in this area require separate petitions for listing each color additive,

21 CFR §§ 8.1 (f), 8.1 (m), 8.4 (c), at an initial fee, subject to refunds, of $2,600 a listing. 21 CFR § 8.50 (c). One respondent, Kolmar Laboratories, Inc., in affidavits submitted to the District Court, asserted that more than 2,700 different formulae would fall under the Commissioner's regulations and would cost some $7,000,000 in listing fees alone. According to the allegations the company also uses 264 diluents which under the challenged regulations must be included as color additives as well. Moreover, a listing is not obtained by mere application alone. Physical and chemical tests must be made and their results submitted with each petition, 21 CFR § 8.4 (c), at a cost alleged by Kolmar of up to $42,000,000. Detailed records must be maintained for each listed ingredient, 21 CFR § 8.26, and batches of listed items must ultimately be certified, again at a substantial fee, 21 CFR § 8.51.

Whether or not these cost estimates are exaggerated [2] it is quite clear that if respondents, failing judicial review at this stage, elect to comply with the regulations and await ultimate judicial determination of the validity of them in subsequent litigation, the amount of preliminary paper work, scientific testing, and recordkeeping will be substantial. The District Court found in denying the motion to dismiss: "I conclude that in a substantial and practical business sense plaintiffs are threatened with irreparable injury by the obviously intended consequences of the challenged regulations, and that to resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and

[2] The Court of Appeals observed that "Very likely these figures are exaggerated . . . ." 360 F. 2d, at 682, n. 5. The District Court stated that "While this amount is immediately suspect, there can be little doubt but that the added recordskeeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs." 235 F. Supp. 648, 652. (Footnote omitted.)

inefficient, not only for the plaintiffs but as well for the public as represented by the defendants." 235 F. Supp. 648, 651.

Like the Court of Appeals, we think that this record supports those findings and conclusions. And as in *Abbott Laboratories, supra,* we have been shown no substantial governmental interest that should lead us to reach a conclusion different from the one we have reached in that case. We hold that this action is maintainable.

Affirmed.

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case.

MR. JUSTICE FORTAS, with whom THE CHIEF JUSTICE and MR. JUSTICE CLARK join, concurring in No. 336, and dissenting in Nos. 39 and 438.

I am in agreement with the Court in No. 336, *Toilet Goods Assn.* v. *Gardner,* that we should affirm the decision of the Court of Appeals for the Second Circuit holding that the authority of the Secretary of Health, Education, and Welfare to promulgate the regulation there involved may not be challenged by injunctive or declaratory judgment action. The regulation (hereinafter referred to as the "access" regulation) was issued under the 1960 Color Additive Amendments to the Federal Food, Drug, and Cosmetic Act. 74 Stat. 397, 21 U. S. C. §§ 321–376. It requires that manufacturers afford employees of the agency access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates, and provides that the Commissioner of Food and Drugs "may immediately suspend certification service" so long as access is denied. 28 Fed. Reg. 6446, 21 CFR § 8.28.

I am, however, compelled to dissent from the decisions of the Court in No. 39, *Abbott Laboratories* v. *Gardner,*

and No. 438, *Gardner* v. *Toilet Goods Assn.* These cases also involve regulations promulgated under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U. S. C. § 301 *et seq.* No. 438, like No. 336, arises under the Color Additive Amendments of 1960. The regulations implement the statutory definition of color additives to include diluents, finished cosmetics and certain hair dyes (the "definition" regulations). The regulation in No. 39 implements amendments to the Act adopted in 1962 by requiring that "every time" the proprietary or trade-mark name of a drug appears on labels and other printed materials, the "established" or generic name must accompany it (the "every time" regulation).

The issues considered by the Court are not constitutional questions. The Court does not rest upon any asserted right to challenge the regulations at this time because the agency lacks authority to promulgate the regulations as to the subject matters involved, or because its procedures have been arbitrary or unreasonable. Its decision is based solely upon the claim of right to challenge these particular regulations at this time on the ground that they are erroneous exercises of the agency's power. It is solely on this point that the Court in these two cases authorizes threshold or pre-enforcement challenge by action for injunction and declaratory relief to suspend the operation of the regulations in their entirety and without reference to particular factual situations.

With all respect, I submit that established principles of jurisprudence, solidly rooted in the constitutional structure of our Government, require that the courts should not intervene in the administrative process at this stage, under these facts and in this gross, shotgun fashion. With all respect, I submit that the governing principles of law do not permit a different result in these cases than

in No. 336. In none of these cases is judicial interference warranted at this stage, in this fashion, and to test—on a gross, free-wheeling basis—whether the content of these regulations is within the statutory intendment. The contrary is dictated by a proper regard for the purpose of the regulatory statute and the requirements of effective administration; and by regard for the salutary rule that courts should pass upon concrete, specific questions in a particularized setting rather than upon a general controversy divorced from particular facts.

The Court, by today's decisions in Nos. 39 and 438, has opened Pandora's box. Federal injunctions will now threaten programs of vast importance to the public welfare. The Court's holding here strikes at programs for the public health. The dangerous precedent goes even further. It is cold comfort—it is little more than delusion—to read in the Court's opinion that "It is scarcely to be doubted that a court would refuse to postpone the effective date of an agency action if the Government could show . . . that delay would be detrimental to the public health or safety." Experience dictates, on the contrary, that it can hardly be hoped that some federal judge somewhere will not be moved as the Court is here, by the cries of anguish and distress of those regulated, to grant a disruptive injunction.

The difference between the majority and me in these cases is not with respect to the existence of jurisdiction to enjoin, but to the definition of occasions on which such jurisdiction may be invoked. I do not doubt that there is residual judicial power in some extreme and limited situations to enjoin administrative actions even in the absence of specific statutory provision where the agency has acted unconstitutionally or without jurisdiction—as distinguished from an allegedly erroneous action. But the Court's opinions in No. 39 and No. 438 appear to proceed on the principle that, even where no consti-

tutional issues or questions of administrative jurisdiction or of arbitrary procedure are involved, exercise of judicial power to enjoin allegedly erroneous regulatory action is permissible unless Congress has explicitly prohibited it, provided only that the controversy is "ripe" for judicial determination. This is a rule that is novel in its breadth and destructive in its implications as illustrated by the present application. As will appear, I believe that this approach improperly and unwisely gives individual federal district judges a roving commission to halt the regulatory process, and to do so on the basis of abstractions and generalities instead of concrete fact situations, and that it impermissibly broadens the license of the courts to intervene in administrative action by means of a threshold suit for injunction rather than by the method provided by statute.

The Administrative Procedure Act [1] and fundamental principles of our jurisprudence [2] insist that there must be some type of effective judicial review of final, substantive agency action which seriously affects personal or property rights. But, "[a]ll constitutional questions aside, it is for Congress to determine how the rights which it creates shall be enforced . . . . In such a case the specification of one remedy normally excludes another." *Switchmen's Union* v. *Board,* 320 U. S. 297, 301 (1943). Where Congress has provided a method of review, the requisite showing to induce the courts otherwise to bring a governmental program to a halt may not be made by a mere showing of the impact of the regulation and the customary hardships of interim compliance. At least in cases

[1] 5 U. S. C. §§ 701–704 (1964 ed., Supp. II).

[2] See *St. Joseph Stock Yards Co.* v. *United States,* 298 U. S. 38, 84 (1936) (concurring opinion of Mr. Justice Brandeis). Hart & Wechsler, The Federal Courts and the Federal System 312–340 (1953). Compare, 4 Davis, Administrative Law Treatise § 28.18 (1958).

where the claim is of erroneous action rather than the lack of jurisdiction or denial of procedural due process, a suit for injunctive or declaratory relief will not lie absent a clear demonstration that the type of review available under the statute would not be "adequate," that the controversies are otherwise "ripe" for judicial decision, and that no public interest exists which offsets the private values which the litigation seeks to vindicate. As I shall discuss, no such showing is or can be made here.

I.

Since enactment of the Federal Food, Drug, and Cosmetic Act in 1938, the mechanism for judicial review of agency actions under its provisions has been well understood. Except for specific types of agency regulations and actions to which I shall refer, judicial review has been confined to enforcement actions instituted by the Attorney General on recommendation of the agency. As the recurrent debate over this technique demonstrates, this restricted avenue for challenge has been deemed necessary because of the direct and urgent relationship of the field of regulation to the public health.[3] It is this avenue that applies with respect to the regulations at issue in the present cases.

The scheme of the Act, in this respect, is as follows: "Prohibited acts" are listed in § 301, 52 Stat. 1042, as amended, 21 U. S. C. § 331. Subsequent sections authorize the Attorney General to institute three types of proceedings. First, under § 302, 52 Stat. 1043, as amended, 21 U. S. C. § 332, he may apply to the district courts of the United States for injunctive relief. If an injunction is violated, jury trial is assured on demand of the accused. Second, under § 304, 52 Stat. 1044, as

[3] See *Ewing* v. *Mytinger & Casselberry*, 339 U. S. 594, 601 (1950).

amended, 21 U. S. C. § 334, the Attorney General may institute libel proceedings in the district courts and seek orders for seizure of any misbranded or adulterated food, drug, device, or cosmetic. Third, criminal prosecution is authorized for violations, but before the Secretary may report a violation to the Attorney General for criminal prosecution, he must afford the affected person an opportunity to present his views. §§ 303, 305, 52 Stat. 1043, 1045, as amended, 21 U. S. C. §§ 333, 335.

The present regulations concededly would be reviewable in the course of any of the above proceedings. Apart from these general provisions, the Act contains specific provisions for administrative hearing and review in the courts of appeals with respect to regulations issued under certain, enumerated provisions of the Act—not including those here involved. These appear in § 701 (f) of the Act, 52 Stat. 1055, as amended, 21 U. S. C. § 371 (f). Section 701, by subdivision (a), contains the Secretary's general authority, exercised in the present cases, to promulgate "regulations for the efficient enforcement of [the Act]." Subdivisions (e) and (f) provide for public hearings, administrative findings, and judicial review in a court of appeals with respect to those regulations specifically enumerated in subsection (e).[4] The Court agrees

[4] 21 U. S. C. § 371 (e) refers only to regulations under § 401, 52 Stat. 1046, as amended, 21 U. S. C. § 341 (identity and quality standards for food), § 403 (j), 52 Stat. 1048, as amended, 21 U. S. C. § 343 (j) (misbranded food purporting to serve special dietary purposes), § 404 (a), 52 Stat. 1048, as amended, 21 U. S. C. § 344 (a) (conditions imposed on manufacture of food as the result of health requirements), § 406, 52 Stat. 1049, as amended, 21 U. S. C. § 346 (tolerances for pesticides), § 501 (b), 52 Stat. 1049, as amended, 21 U. S. C. § 351 (b) (deviations from strength, quality, or purity standards, for drugs), § 502 (d), 52 Stat. 1050, as amended, 21 U. S. C. § 352 (d) (warnings with respect to habit-forming drugs), and § 502 (h), 52 Stat. 1051, as amended, 21 U. S. C. § 352 (h)

that this procedure applies only to the enumerated types of regulations and that the present regulations are unaffected. Then, as to the enumerated regulations which are subject to judicial review—and only as to them—subparagraph (6) of subsection (f) specifies that "[t]he remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law." This "saving clause" does not apply or refer to regulations other than those enumerated, and the Court's argument to the contrary is inconsistent with the clear wording and placement of the clause.[5]

(packing and labeling of deteriorative drugs). In addition, particular sections expressly incorporate the §§ 371 (f) and (g) procedures: § 506, 55 Stat. 851, as amended, 21 U. S. C. § 356 (certain portions of regulations pertaining to certification of drugs containing insulin), § 507, 59 Stat. 463, as amended, 21 U. S. C. § 357 (with respect to regulations dealing with antibiotic drugs). Finally, § 505 (h), 52 Stat. 1053, as amended, 21 U. S. C. § 355 (h) provides that denials of certification for new drugs may be reviewed in the courts of appeals.

[5] The saving clause, subdivision (6) of subsection (f), specifically and carefully refers to the "remedies provided for in *this* subsection." (Emphasis added.) Its wording and placement would be anomalous if the saving clause were intended to have general applicability. The legislative history of the saving clause, and particularly the failure of more broadly conceived provisions to obtain acceptance by the Congress, corroborates the evidence of the clause's ultimate language and position that it was to have restricted application. See Dunn, Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record 184, 225, 609–610 (1938) (hereinafter cited as Dunn).

Contrary to the majority's contention, the reason for the clause and for its location in subsection (f) is clear and common-sensical. It was intended to save the remedies of injunction and declaratory judgment where the agency promulgated a subsection (e) regulation without the hearings and findings needed to permit review in the Court of Appeals. In short, as its placement indicates, it was intended to complete the scheme of pre-effectiveness review as to those carefully enumerated regulations with respect to which Con-

At various times, § 701 has been amended to include types of regulations in addition to those initially subjected to § 701 (f). Indeed, in the congressional action which included enactment of statutory provisions here in issue, the 1960 Color Additive Amendments, 74 Stat. 397, Congress amended § 701 (e), 21 U. S. C. § 376 (e) to include certain of the regulations authorized by the Color Additive Amendments. But, significantly, these did not include the regulations at issue in No. 336 and No. 438. The same is true with respect to the later Drug Amendments of 1962, 76 Stat. 780. Subsection (e) was again enlarged, but the provision involved in No. 39 was not included. These actions were taken in the course of vigorous debate as to the enforcement and review provisions which should be enacted with respect to the 1960 and 1962 amendments.

On a number of occasions Congress considered and rejected the proposal that district courts be given power to restrain by injunction the enforcement of regulations.[6] The bill that became law in 1938 originally contained provisions for hearings and judicial review in the district courts of certain specified types of regulations (substantially those later enacted as § 701, *supra*). District courts were also empowered to enjoin "any regulation promulgated in accordance with section 24" (which would include the regulations at issue in these cases,

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gress deemed pre-enforcement review to be advisable. It has no broader application.

It will come as a shock to the agency, Congress, and practitioners, that for almost 30 years this undetected, omnibus "saving clause" has slumbered in the Act.

[6] Section 23 of S. 2800, introduced in the 73d Cong., 2d Sess. (1934), for example, was such a provision and was expressly discussed on the floor of the Senate. 78 Cong. Rec. 8958–8959 (1934); Dunn 157–159. A successor bill, S. 5, 74th Cong., 1st Sess. (1935), contained a similar provision, § 702, and was approved by the Senate. 79 Cong. Rec. 8356 (1935). See Dunn 330–331, 510.

262-921 O - 68 - 15

promulgated under § 701 (a)). S. 5, 75th Cong., 1st Sess. (1937). The House Committee eliminated the latter provision and substituted what became subsection (f). This draft authorized review in a district court of regulations under subsection (e) and of those orders only.[7] Even this restricted provision for enjoining certain regulations met with bitter opposition because it "would postpone indefinitely the consumer protection" or would "hamstring" the Act's enforcement and "amount to a practical nullification . . . of the bill." [8] The Conference Committee then drafted the bill which was enacted, including the House revision of the review provision which became § 701 except for a significant change: So concerned was the Congress lest the administration of the law should be subject to judicial intervention that even with respect to the specified regulations in subsection (e) the reviewing power was placed in the courts of appeals rather than in the district courts.[9] This was to meet the criticism that "a single district judge could be found who would issue an injunction." But this is exactly what the Court today decrees. Rejected along with the original House proposal was the suggestion from the Department of Justice, set out at 83 Cong. Rec. 7892 (1938), that the Congress should leave review in the hands of the district courts' traditional injunctive powers—although the Court today resuscitates that lost cause, too.

As this Court held in *Ewing* v. *Mytinger & Casselberry*, 339 U. S. 594, 600–601 (1950), "This highly selective manner in which Congress has provided [in this Act] for judicial review reinforces the inference that the only review of the issue of probable cause [for seizure] . . . was the one provided in the libel suit."

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[7] H. R. Rep. No. 2139, 75th Cong., 3d Sess. (1938).

[8] *Id.*, Pt. II (minority statement).

[9] H. R. Conf. Rep. No. 2716, 75th Cong., 3d Sess. (1938).

In evaluating the destructive force and effect of the Court's action in these cases, it is necessary to realize that it is arming each of the federal district judges in this Nation with power to enjoin enforcement of regulations and actions under the federal law designed to protect the people of this Nation against dangerous drugs and cosmetics. Restraining orders and temporary injunctions will suspend application of these public safety laws pending years of litigation—a time schedule which these cases illustrate.[10] They are disruptive enough, regardless of the ultimate outcome. The Court's validation of this shotgun attack upon this vital law and its administration is not confined to these suits, these regulations, or these plaintiffs—or even this statute. It is a general hunting license; and I respectfully submit, a license for mischief because it authorizes aggression which is richly rewarded by delay in the subjection of private interests to programs which Congress believes to be required in the public interest. As I read the Court's opinion, it does not seriously contend that Congress authorized or contemplated this type of relief. It does not rest upon the argument that Congress intended that injunctions or threshold relief should be available. The Court seems to announce a doctrine, which is new and startling in administrative law, that the courts, in determining whether to exercise jurisdiction by injunction, will not look to see whether Congress intended that the parties should resort to another avenue of review, but will be governed by whether Congress has "prohibited"

[10] The "every time" regulation was published about four years ago, on June 20, 1963, 28 Fed. Reg. 6375. As a result of litigation begun in September of 1963, it has not yet been put into force. The "definition" regulations and the "access" regulation with respect to color additives were published on June 22, 1963, 28 Fed. Reg. 6439, 6446. Litigation was begun in November of 1963, and the regulations are not yet operative.

injunctive relief. The Court holds that "judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." As authority for this, the Court produces little support. *Board of Governors* v. *Agnew,* 329 U. S. 441 (1947), involved removal from office of certain bank directors. Had the Court not authorized review, the aggrieved individuals could only test the correctness of the administrator's decision by ignoring it and risking a prison term of five years. No evidence of congressional hostility to review was adduced.[11] *Heikkila* v. *Barber,* 345 U. S. 229 (1953), does not even remotely support the Court's contention. On the contrary, it holds that a provision in the Immigration Act of 1917 to the effect that the decision of the Attorney General is "final" in deportation cases *precludes* direct attack upon a deportation order by means of suits for injunction or declaratory relief. What might be termed the other personal liberties cases relied upon by the Court are discussed below. But in cases like the present, where courts and administrative agencies both function, it has always—to this date—been accepted that the intention of Congress—not its mere failure to prohibit—will be faithfully searched out by the courts and will be implemented except in the unusual and extraordinary situations where the result would be essentially to leave the parties without any adequate right to judicial review. Compare *Leedom* v. *Kyne,* 358 U. S. 184

[11] As to the other nonpersonal liberty cases cited by the Court: In *Shields* v. *Utah Idaho Central R. Co.,* 305 U. S. 177 (1938), the Government did not oppose resort to the injunction remedy, and the Court enumerated special circumstances why that remedy was peculiarly needed. *Id.,* at 183–184. And in *Stark* v. *Wickard,* 321 U. S. 288 (1944), the Court noted that the aggrieved parties had no other forum in which to contest the order in question, and it found "plain" evidence of a congressional intent to allow review.

(1958), with *Switchmen's Union* v. *Board, supra; Myers* v. *Bethlehem Shipbuilding Corp.*, 303 U. S. 41 (1938); and *Adams* v. *Nagle*, 303 U. S. 532 (1938).

In effect, the Court says that the Food, Drug, and Cosmetic Act has always authorized threshold injunctions or declaratory judgment relief: that this relief has been available since the enactment of the law in 1938, and that it would have been granted in appropriate cases which are "ripe" for review. I must with respect characterize this as a surprising revelation. Despite the highly controversial nature of many provisions of such regulations under the Act, this possibility has not been realized by ingenious and aggressive counsel for the drug and food and cosmetics industries until this time. The Court's opinion and the briefs cite only a single case in which such relief has been granted prior to the present cases, and that preceded enactment of the present statutory scheme. *Morgan* v. *Nolan*, 3 F. Supp. 143 (D. C. S. D. Ind. 1933), aff'd, 69 F. 2d 471 (C. A. 7th Cir. 1934). The fact of the matter is that, except for the instances enumerated in §§ 701 (e) and (f), the avenue for attack upon the statute and regulations has been by defense to specific enforcement actions by the agency. Congress has been well aware of this for more than a generation that the statute has been in effect.[12]

Where a remedy is provided by statute, I submit that it is and has been fundamental to our law, to judicial administration, to the principle of separation of powers in our Constitution, that the courts will withhold equitable or discretionary remedies unless they conclude that the statutory remedy is inadequate. Even then, as the

[12] Indeed, Congressman Lea, principal floor manager for the bill which became the 1938 Act, told his colleagues that the review provisions of the new bill were not retroactive, and that pre-existing regulations were therefore unreviewable unless re-enacted. 83 Cong. Rec. 7776–7777 (1938).

Court recognizes, the case must be "ripe" or appropriate for threshold judicial review. Any other doctrine than this—any doctrine which so far departs from judicial restraint and judicial recognition of the power of the Congress and the administrative agencies—is bound to be disruptive. It would mean that provisions in regulatory statutes and regulations of a wide variety of administrative agencies would be subject to threshold attack because Congress has not, in addition to providing judicial review by prescribed procedures, also said to the courts, "thou shalt not enjoin *in limine*."

The limited applicability of the Administrative Procedure Act in these cases is entirely clear. That Act requires that unless precluded by Congress final agency action of the sorts involved here must be reviewable at some stage, and it recognizes that such review must be "adequate." It merely presents the question in these cases. It does not supply an answer. Certainly, it would be revolutionary doctrine that the Administrative Procedure Act authorizes threshold suits for injunction even where another and adequate review provision is available. The Court refers to the Administrative Procedure Act as "seminal." It is, in a real sense; but its seed may not produce the lush, tropical jungle of the doctrine that the Court will permit agency action to be attacked *in limine* by suit for injunction or declaratory action unless Congress expressly prohibits review of regulatory action. See 3 Davis, Administrative Law Treatise § 22.08 (1958).

I submit that if we are to judge and not to legislate policy, we should implement and not contradict the program laid out by the Congress. Congress did not intend that the regulations at issue in this case might be challenged in gross, apart from a specific controversy, or in the district courts, or by injunction or declaratory judgment action. On the contrary, the clear intent was that

the regulations, being to protect the consumer from unsafe, potentially harmful, and "misbranded" foods, drugs, devices, and cosmetics, were to be subject to challenge only by way of defense to enforcement proceedings. It was Congress' judgment, after much controversy, that the special nature of the Act and its administration required this protection against delay and disruption. We should not arrogate to ourselves the power to override this judgment. Not a single case cited by the majority in which agency action was held reviewable arose against this kind of background of legislative hostility to threshold review in the district courts.

The Court is in error, I submit, in its approach to this problem; and, as I shall attempt to show, it is in error in its decision that, even given this permissive approach to the use of judicial injunctive power, these controversies are "ripe" or appropriate for decision.

II.

I come then to the questions whether the review otherwise available under the statute is "adequate," whether the controversies are "ripe" or appropriate for review in terms of the evaluation of the competing private and public interests. I discuss these together because the questions of adequacy and ripeness or appropriateness for review are interrelated. I again note that no constitutional issues are raised, and, indeed, no issues as to the authority of the agency to issue regulations of the general sort involved. The only issue is whether that authority was properly exercised.

There is, of course, no abstract or mechanical method for determining the adequacy of review provisions. Where personal status or liberties are involved, the courts may well insist upon a considerable ease of challenging administrative orders or regulations. Cf. *Rusk* v. *Cort*, 369 U. S. 367 (1962); but cf. *Heikkila* v. *Barber*,

345 U. S. 229 (1953).[13] But in situations where a regulatory scheme designed to protect the public is involved, this Court has held that postponement of the opportunity to obtain judicial relief in the interest of avoiding disruption of the regulatory plan is entirely justifiable. *Ewing* v. *Mytinger & Casselberry,* 339 U. S. 594 (1950); cf. *Myers* v. *Bethlehem Shipbuilding Corp.,* 303 U. S. 41 (1938).[14] The *Ewing* case dramatically illustrates the point. It involves the same statute and enforcement plan as are now before us. Appellee filed suit in the United States District Court to restrain enforcement of the provision of the Food, Drug, and Cosmetic Act which authorizes multiple seizure of misbranded products. Appellee claimed that the provision was unconstitutional under the Due Process Clause, and that the agency had acted arbitrarily "in instituting" (through the Attorney General) multiple seizures without affording appellee an opportunity for hearing as to whether there was "probable cause" for the seizures. A three-judge district court was convened. It held for appellee on both issues and granted an injunction. This Court reversed on the grounds that no hearing is necessary for the administrative determination of probable cause, and that, in any event, the District Court had no jurisdiction to review that determination.[15]

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[13] See Jaffe, Judicial Control of Administrative Action 372.

[14] In *Ewing,* 339 U. S., at 599, a case under the Federal Food, Drug, and Cosmetic Act, the Court held "it is not a requirement of due process that there be judicial inquiry before discretion can be exercised. It is sufficient, where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination. *Phillips* v. *Commissioner,* 283 U. S. 589, 596–597; *Bowles* v. *Willingham,* 321 U. S. 503, 520; *Yakus* v. *United States,* 321 U. S. 414, 442–443."

[15] Where Congress has created a right but provided no avenue for judicial protection against its obliteration, suit for injunctive relief may be available under 28 U. S. C. § 1337, relating to pro-

It is no answer to *Ewing* to point out, as the Court does, that the precise determination attacked by the plaintiff was that of probable cause for recommending multiple seizures. The important point is that the Court held that the processes of the District Court could not be invoked except in the enforcement action provided by Congress. The following quotation from MR. JUSTICE DOUGLAS' opinion for the Court demonstrates the controlling force of *Ewing* in the present case:

> "Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the Act. Congress made numerous administrative determinations under the Act reviewable by the courts. . . . This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided in the libel suit. Cf. *Switchmen's Union* v. *Board,* 320 U. S. 297, 305–306. . . . If the District Court can step in, stay the institution of seizures, and bring the administrative regulation to a halt until it hears the case, the public will be denied the speedy protection which Congress provided by multiple seizures." 339 U. S., at 600–601.

In *Ewing,* the company's only recourse was to defend in the seizure actions, availing itself of consolidation of the multiple suits if it so desired. 339 U. S., at 602.

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ceedings "arising under any Act of Congress regulating commerce or protecting trade and commerce against restraints and monopolies." See *Leedom* v. *Kyne,* 358 U. S. 184 (1958), where this Court authorized suit in the district courts to set aside an NLRB certification of a bargaining unit in which the Board had included both supervisory and nonsupervisory personnel—concededly without authority of statute. But cf. *Switchmen's Union* v. *Board,* 320 U. S. 297 (1943).

Despite the hardship and destructive publicity of multiple seizures—a more serious variety of the kind of hardship which seems profoundly to affect the Court in the present cases—this Court refused to hold that the remedy of judicial review by defense in these actions was inadequate. On the contrary, it held that "Congress weighed the potential injury to the public from misbranded articles against the injury to the purveyor of the article from a temporary interference with its distribution and decided in favor of the speedy, preventive device of multiple seizures." 339 U. S., at 601.

I submit that this Court's action in Nos. 39 and 438 sharply departs from *Ewing* and from the principles of judicial restraint and respect for congressional enactments and administrative agencies which have to this day been fundamental to our jurisprudence. The Court refers in passing to the injunctions here as "traditional avenues of judicial relief." But there is nothing "traditional" about the courts providing injunctive relief against agency action in situations where the Congress has prescribed another avenue which is available to the plaintiffs. Eloquent testimony of this is the paucity of pertinent precedents.

The three decisions of this Court principally relied upon by the majority here are primarily noteworthy for their difference rather than their analogy. In each of them the particular statutory scheme involved expressly provided for the jurisdiction of the court in which the suit was brought. In none of them is the action maintained despite congressional provision of another and different remedy.

Columbia Broadcasting System v. *United States*, 316 U. S. 407 (1942), concerned a regulation promulgated by the FCC which would have refused a license to any station which entered into defined types of network contracts. CBS, a network and not a station licensee,

brought an action to enjoin enforcement of the regulation, claiming that it was beyond the Commission's power. The action was brought under § 402 (a) of the Communications Act itself (48 Stat. 1093) which makes applicable the provisions of the Urgent Deficiencies Act to "suits to enforce, enjoin," etc., any order of the Commission with certain exceptions not here relevant. Thus, the statute itself provided for injunctive action against orders of the Commission. The only problem in the case was whether the particular order was "reviewable" at all on suit of CBS and, if so, whether the action was premature—not whether the courts might, consistently with the congressional scheme, entertain suit for injunction in proper circumstances, because that was settled by specific provisions in the Act. The Court held that the action could be maintained. And it held that CBS had no adequate alternative remedy. At most, CBS could have intervened in a proceeding controlled by a station applying for a license—if there were such a proceeding.[16] The Court therefore held that CBS could challenge the regulation before it was invoked against a licensee. This is a far cry from the present cases in which *despite* the absence of statutory authorization of district court jurisdiction over the injunctive procedure, and in face of the regulatory design, the manufacturers seek to invoke the courts' general equity power to override what appears to be the studied and deliberate intention of the Congress.

In *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956), the FCC promulgated a rule limiting to five the number of television stations which would be licensed to a single person. The same day it denied, on the basis of the rule, an application by Storer, which owned five stations, for an additional station. Storer appealed, not

[16] As a leading commentator has noted, the basic issue was that of CBS' standing. Jaffe, *op. cit. supra,* at 394.

to the District Court, but to the Court of Appeals, for review of the Commission's rulemaking order. The Court of Appeals had jurisdiction by specific statutory provision to entertain petitions to review final orders of the Commission upon application of "[a]ny party aggrieved." 64 Stat 1130, 5 U. S. C. § 1034. This Court held that Storer had standing to maintain the petition for review, that the rule was a "final order" for review purposes and that the controversy with respect to the limitation rule was "ripe" for review. Again, the important point to note is that the case did not involve the assertion of district court jurisdiction in the absence of statute, or the overriding of administrative design or congressional intent. Storer utilized a procedure expressly made available by the statute. It sought review in the Court of Appeals where the Commission action was reviewed on the basis specified by statute, including the weight given to the agency findings and record. It did not commence a separate action, not provided for in the statute, in which the District Court's original jurisdiction was invoked. *Storer,* in brief, involves an action pursuant to the statute, and not in conflict with its plan as is true of the present cases.

The third case is *Frozen Food Express* v. *United States,* 351 U. S. 40 (1956). The ICC issued an order, after investigation and hearing, listing commodities which it found not to be "agricultural" for purposes of an exemption from the requirement of obtaining a certificate of convenience and necessity under the Interstate Commerce Act. A motor carrier sued in the United States District Court to enjoin and set aside the Commission's order. The statute under which the suit was brought expressly gives the district courts jurisdiction to enjoin, etc., "any order of the Interstate Commerce Commission." 28 U. S. C. § 1336. Accordingly, here, too, there was no question of the courts furnishing a forum which the

regulatory statute did not provide. This case, like *Columbia Broadcasting* and *Storer, supra,* therefore, does not touch the key problem of the instant cases. It is relevant only on the issue of "ripeness"—an intensely particularized inquiry involving considerations which, as I shall discuss, should lead to rejection of the instant actions.[17]

Considering the impact of these three cases on the problem of "ripeness" in the instant cases, I first note that each of these three cases is, in effect, two-dimensional. The meaning, effect, and impact of the accused rule or decision are clear, simple, and obvious. None is part of the warp and woof of an elaborate administrative pattern, intimately woven into the congressional design. None of them is apt to take different shape or to be modified by practical administrative action. None of them is subject to the give-and-take of the administrative process as it works, for example, in the realities of the complex world of food, drug, and cosmetic regulation. None of them is subject to exception upon application. None of them depends upon the independent judgment of the Attorney General for enforcement. These are stark, simple, two-dimensional regulations which do not depend upon the specifics of a particular situation for judgment as to their consonance with statutory authority nor are they subject to change in the process of administrative application. In short, in the three cases the courts proceeded within the procedural framework enacted by Congress, and the circumstances were such that the courts could make a sensible, realistic judgment as to whether the administrative rule matched the statu-

[17] MR. JUSTICE HARLAN dissented in *Frozen Food Express* on the ground that "the case falls squarely within those carefully developed rules which require that judicial intervention be withheld until administrative action has reached its complete development." 351 U. S., at 45.

tory authority.[18] These factors are entirely absent in the present cases. Analysis of the regulations in the present cases will, I believe, demonstrate the point.

In No. 336 (involving the regulation requiring "free access" to plants, processes, and formulae with respect to all "color additives") the Court concludes "that the legal issue as presently framed is not appropriate for judicial resolution." It bases its conclusion upon two factors: (1) that the Secretary may or may not order inspection, and, if denied access, he may or may not decide to use the authority of the regulation to withdraw or suspend certification without which the manufacturer may not continue his business in the products; and (2) that judgment as to whether the regulation is authorized depends upon an understanding of the types of enforcement problems encountered by FDA, the need for supervision and the safeguards devised to protect legitimate trade secrets. The Court also says that it is an adequate remedy for the manufacturer to defer challenge until after access is demanded and denied and further certification services by the agency are suspended. The suspension of certification services means a shutdown, at least *pro tanto,* but the Court says, with an optimism which is probably not shared by the industry, that "prompt" challenge through administrative procedure and court review can then be had.

Precisely the same considerations demonstrate, I submit, that the regulations in No. 39 and No. 438 should similarly be immune from attack in these suits. In No. 438, the accused regulations were also issued under § 701 (a), the general power to promulgate regulations for the efficient administration of the Act, specifically the 1960 amendments to promote "safety-in-use" of color

[18] Although *Frozen Food Express* involved problems of definition, they were not comparable to the complex, subtle, technical considerations involved in the "definition" or "every time" regulations here.

additives. As the Court states, by the regulations in No. 438 the Commissioner "amplified the statutory definition" of color additives to include diluents and certain cosmetics and hair dyes. By provisions in the statute, 74 Stat. 399, 21 U. S. C. § 376 (a)(1)(A), a product containing a "color additive" shall be deemed "adulterated" unless the color additive and its proposed use have been submitted to FDA, tested and listed in an FDA regulation as safe and unless the particular additive comes from a certified batch, or has been exempted from certification. Distribution of a product without compliance runs the risk of seizure, injunction, or criminal prosecution upon action of the Attorney General. Again, there is no question that the Commissioner could refine and "amplify" the definition of "color additives." The argument is whether he could do it in this particular way, to include these particular items.

Now, with all respect, I submit that this controversy is clearly, transparently and obviously unsuited to adjudication by the courts *in limine* or divorced from a particular controversy. Every reason advanced in No. 336 (the "access" regulation) is applicable here with equal or greater force to repel this effort to secure judicial review at this stage. (1) In No. 336, the Court pointed out that the Commissioner might or might not demand access and withdraw certification in a particular case. Similarly, in the present case it is impossible to ascertain at this stage how and whether in a particular situation the regulation will apply to that situation. First and most obvious is the fact that any manufacturer may apply for an exemption from the regulation if, as applied to his particular situation, it is unfair or unduly burdensome or—more significantly—if it falls outside of the statutory intendment. And even more than in the case of the access regulation, the definitional regulation is not self-enforcing. Indeed, in respect of the access

regulation the Commissioner may resort to a measure of self-help by withholding certification services, whereas if the FDA wishes to take action against a manufacturer who refuses to submit a "color additive" to the agency on the ground that it is not covered, the agency must institute an independent proceeding in court which it can do only if the Attorney General agrees with its conclusions.

(2) In No. 336, the Court was influenced by the obvious fact that adjudication of the legality of the access regulation requires an understanding of the enforcement problems of the agency and the actual needs for supervision. I agree. But I respectfully suggest that if this is true of a simple investigatory and enforcement regulation like that requiring access to plants and processes, it is much more compelling in respect of a complex regulation defining "color additives." How, for example, can a court possibly judge whether a substance should be included in the definition outside of the context of a specific controversy and in the absence of detailed information as to the agency problem?

The Court, however, describes the issue in No. 438 as "a straightforward legal one: what general classifications of ingredients fall within the coverage of the Color Additive Amendments?" The Court says that "this is not a situation in which consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations." With all respect, these statements are totally divorced from reality. For example, the statute itself includes within the definition of a "color additive" any "other substance" which "when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting color thereto." § 201 (t)(1), 74 Stat. 397, 21 U. S. C. § 321 (t)(1). Can it be seriously

contended that the question, for example, whether a particular diluent—solvent or substance serving to dilute—meets this definition is "a straightforward legal one," decision of which would not "necessarily be facilitated" if raised in specific context? I note that the Court recognizes the frailty of its pronouncement in a footnote in which it says that "If in the course of further proceedings the District Court is persuaded that technical questions are raised that require a more concrete setting for proper adjudication, a different issue will be presented"! But I submit, with respect, that this question which, even standing alone, would dictate our rejection of the action in No. 438, can and must be faced, here and now; and the answer to it is clear and obvious. It is clear beyond question, merely on the basis of the nature of the agency action, that these regulations on their face raise questions which should not be adjudicated in the abstract and in the general, but which require a "concrete setting" for determination. A threshold injunction is entirely unsuitable in these circumstances. It places the administration of a public-safety statute at the mercy of counsel's ability to marshall and deploy horrible examples which logic may accommodate, but the reality of administration would repel. Our training as lawyers and judges, our respect for the administrative process, and our awareness of the complexities of life should warn us not to fall into the trap of abstract, generalized, gross review.

The regulation in No. 39 relates to a 1962 amendment to the Act requiring manufacturers of prescription drugs to print on the labels or other printed material, the "established name" of the drug "prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug." § 502 (e)(1), 76 Stat. 790, 21 U. S. C. § 352 (e)(1). Obviously, this requires some elucidation, either case-by-case or by gen-

262-921 O - 68 - 16

eral regulation or pronouncement, because the statute does not say that this must be done "every time," or only once on each label or in each pamphlet, or once per panel, etc., or that it must be done differently on labels than on circulars, or doctors' literature than on directions to the patients, etc. This is exactly the traditional purpose and function of an administrative agency. The Commissioner, acting by delegation from the Secretary, took steps to provide for the specification. He invited and considered comments and then issued a regulation requiring that the "established name" appear every time the proprietary name is used. A manufacturer—or other person who violates this regulation—has mislabeled his product. The product may be seized; or injunction may be sought; or the mislabeler may be criminally prosecuted. In any of these actions he may challenge the regulation and obtain a judicial determination.

The Court, however, moved by petitioners' claims as to the expense and inconvenience of compliance and the risks of deferring challenge by noncompliance, decrees that the manufacturers may have their suit for injunction at this time and reverses the Third Circuit. The Court says that this confronts the manufacturer with a "real dilemma." But the fact of the matter is that the dilemma is no more than citizens face in connection with countless statutes and with the rules of the SEC, FTC, FCC, ICC, and other regulatory agencies. This has not heretofore been regarded as a basis for injunctive relief unless Congress has so provided. The overriding fact here is—or should be—that the public interest in avoiding the delay in implementing Congress' program far outweighs the private interest; and that the private interest which has so impressed the Court is no more than that which exists in respect of most regulatory statutes or agency rules. Somehow, the Court has con-

cluded that the damage to petitioners if they have to engage in the required redesign and reprint of their labels and printed materials without threshold review outweighs the damage to the public of deferring during the tedious months and years of litigation a cure for the possible danger and asserted deceit of peddling plain medicine under fancy trademarks and for fancy prices which, rightly or wrongly, impelled the Congress to enact this legislation. I submit that a much stronger showing is necessary than the expense and trouble of compliance and the risk of defiance. Actually, if the Court refused to permit this shotgun assault, experience and reasonably sophisticated common sense show that there would be orderly compliance without the disaster so dramatically predicted by the industry, reasonable adjustments by the agency in real hardship cases, and where extreme intransigence involving substantial violations occurred, enforcement actions in which legality of the regulation would be tested in specific, concrete situations. I respectfully submit that this would be the correct and appropriate result. Our refusal to respond to the vastly overdrawn cries of distress would reflect not only healthy skepticism, but our regard for a proper relationship between the courts on the one hand and Congress and the administrative agencies on the other. It would represent a reasonable solicitude for the purposes and programs of the Congress. And it would reflect appropriate modesty as to the competence of the courts. The courts cannot properly—and should not—attempt to judge in the abstract and generally whether this regulation is within the statutory scheme. Judgment as to the "every time" regulation should be made only in light of specific situations, and it may differ depending upon whether the FDA seeks to enforce it as to doctors' circulars, pamphlets for patients, labels, etc.

I submit, therefore, that this invitation to the courts to rule upon the legality of these regulations in these actions for injunction and declaratory relief should be firmly rejected. There is nothing here approaching the stringent showing that should be required before the courts will undertake to provide a remedy that Congress has not authorized but which, on the contrary, it has deliberately declined to afford. Those challenging the regulations have a remedy and there are no special reasons to relieve them of the necessity of deferring their challenge to the regulations until enforcement is undertaken. In this way, and only in this way, will the administrative process have an opportunity to function—to iron out differences, to accommodate special problems, to grant exemptions, etc. The courts do not and should not pass on these complex problems in the abstract and the general—because these regulations peculiarly depend for their quality and substance upon the facts of particular situations. We should confine ourselves—as our jurisprudence dictates—to actual, specific, particularized cases and controversies, in substance as well as in technical analysis. And we should repel these attacks, for we have no warrant and no reason to place these programs, essential to the public interest, and many others which this Court's action today will affect, at the peril of disruption by injunctive orders which can be issued by a single district judge. In short, the parties have an "adequate remedy" to test the regulations; these controversies are not "ripe" for judicial decision; and it is not appropriate that the courts should respond to the call for this private relief at disproportionate burden to the public interest. With all respect, we should refuse to accept the invitation to abandon the traditional insistence of the courts upon specific, concrete facts, and instead entertain this massive onslaught in which it will be utterly impossible to make the kind of discrete judgments which are

within judicial competence. With all respect, we should not permit the administration of a law of the Congress to be disrupted by this nonadjudicable mass assault.

MR. JUSTICE CLARK, dissenting.

I join my Brother FORTAS' dissent. As he points out the regulations here merely require common honesty and fair dealing in the sale of drugs. The pharmaceutical companies, contrary to the public interest, have through their high-sounding trademarks of long-established medicines deceitfully and exorbitantly extorted high prices therefor from the sick and the infirm. Indeed, I was so gouged myself just recently when I purchased some ordinary eyewash drops and later learned that I paid 10 times the price the drops should have cost. Likewise, a year or so ago I purchased a brand name drug for the treatment of labyrinthitis at a cost of some $12, which later I learned to buy by its established name for about $1.

The Court says that its action in so sabotaging the public interest is required because the laboratories will have to "change all their labels, advertisements, and promotional materials . . . destroy stocks of printed matter; and they must invest heavily in new printing type and new supplies." I submit that this is a lame excuse for permitting the continuance of such a dishonest practice. Rather than crying over the plight that the laboratories have brought on themselves the Court should think more of the poor ailing folks who suffer under the practice. I dare say that the practice has prevented millions from obtaining needed drugs because of the price. The labels involved here mislead the public by passing off ordinary medicines as fancy cures. The Commissioner was right in directing that the practice be stopped.

I hope that the Congress will not delay in amending the Act to close this judicial exition that the Court has unwisely opened up for the pharmaceutical companies.